TAB A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re:	)	
PHARMACEUTICAL INDUSTRY	)	CA No. 01-12257-PBS
AVERAGE WHOLESALE PRICE	)	MDL No. 1456
LITIGATION	)	Pages 1 - 216

BENCH TRIAL - DAY ONE

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
November 6, 2006, 9:15 a.m.

LEE A. MARZILLI and TIMOTHY J. WILLETTE
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

I N D E X

MR. BERMAN: Okay.

THE COURT: So what I should be focusing on is, that looks like there's a spread of between, I don't know, 20 and 30 percent, somewhere in there, right, for many years? And what you're saying is, it went dramatically up in 2001?

MR. BERMAN: That's correct.

THE COURT: So to the extent you say there's a market expectation of no more than 30 percent, the problem arises -- I need to go drug by drug on when the problem arises, if at all.

MR. BERMAN: Dr. Hartman has done that for you. So when he gives you a table, there will be years on each drug in which there will be no liability under Class 3 because it did not exceed 30 percent, and then there will be years that there will be liability. That will all be laid out for you.

Let's take a look at another drug called Blenoxane.

THE COURT: Still BMS?

MR. BERMAN: Still BMS. There's three or four drugs, and then I'll be almost done with BMS.

Let me stop right here for a second. Will you blow this up.

THE COURT: Are you standing because you have a bad back or because there's no room?

FROM THE FLOOR: No chair.

TAB B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris
	Chief Magistrate Judge Marianne B. Bowler

DIRECT TESTIMONY OF RAYMOND S. HARTMAN

21. These allegations suppose that those entities being incentivized could and would move market share. Considerable discovery materials, industry literature and academic research support these allegations.[22] This Court has explicitly recognized this alleged behavior, stating[23]

> "Because doctors are involved as both retailers and as prescribing physicians, manufacturers, realizing the purchasing power of physicians, provide them with rebates, leading to large profits for the doctors on the prescription and administration of certain drugs. These profits now allegedly comprise a large percentage of these doctors' income; according to Hartman, two thirds of the income of practice-based oncologists comes from the mark-up on injectable drugs. … Some experts have commented that 'the financial incentives created by this profitability played a large and problematic role in prescribing decisions' from 1998-2003 because 'prescribers responded to these high margins by tending towards administering more (and more expensive) drugs than might be medically necessary or optimal for the health of the patient.' …
>
> In summary, when medical benefit expenditure data are poorly monitored and 'tracking patient data is nearly impossible', and when this is widely known, possibilities for mischief and abuse arise. That appears to be the case for physician-administered drugs adjudicated under the medical benefit (Berndt ¶ 191)."

22. I discuss below (Section III.D) the extent to which Defendants believed and relied upon the AWP scheme to incentivize physicians to move market share and thereby benefit from the alleged scheme. I note that the spread could be manipulated by either artificially inflating the AWP (to which reimbursement was formally linked under Part B) everything else equal; by reducing ASP, everything else equal; or by doing both. Of course, from the Defendants' perspective, the most profitable strategy to increase spread would be to artificially inflate the AWP, holding ASP constant. In that case, the manufacturer would not decrease the revenue per unit sold while still increasing the incentives to move market share. These alternative methods

[22] See footnote 20 for two recent academic articles further supporting this finding.

[23] *Memorandum and Order*, pp. 30-31.

of increasing the spread were recognized in the 2003 Report to the Congress from the Medicare Payment Advisory Commission (MedPAC) as follows:[24]

> "In percentage terms, the biggest difference between the listed AWP for drugs and actual prices paid by physicians and suppliers tends to occur with generic drugs or brand name drugs for which there are alternatives available in the same therapeutic class. For these drugs, **manufacturers compete to increase their market share. This competition can take two forms. A manufacturer may raise the AWP for its product without changing the price charged to purchasers.** Although the manufacturer's profit per dose will not increase with the rise in the listed price, the bigger difference between providers' acquisition costs and Medicare payment leads to higher profits for providers when they choose the manufacturer's product over its competitor. At the same time, coinsurance payments charged to beneficiaries will rise as the AWP increases. A hearing before the House Energy and Commerce Subcommittee on Health highlighted this outcome on September 21, 2001. One chemotherapy drug, Vincasar, which had an AWP of $740, was sold to physicians for $7.50 per dose. The beneficiary's copayment (about $150) was about 20 times providers' acquisition cost. **Possibly in response to increasing scrutiny of drug pricing practices by the courts, some manufacturers have adopted an alternative marketing strategy. They leave the AWPs at existing levels, and offer larger discounts directly to physicians who choose their drugs** over products offered by competitors. In this case, the manufacturers' profit per unit dose will be less, but overall profits increase if the discounts result in increased market share. On May 5, 2003, the Office of Inspector General (2003) issued voluntary compliance guidelines for pharmaceutical manufacturers.[25] If a manufacturer manipulates the AWP to increase federal payments to its customers, the federal antikickback statute is implicated. In other words, it is illegal for a manufacturer knowingly to establish or maintain an AWP if one purpose is to manipulate the spread to induce customers to purchase its products (emphasis added)."

23. To date, the most publicized example of fraudulent AWP price inflation has been litigation against TAP Pharmaceuticals for their drug Lupron, which is not a Track 1 drug. The methods by which the "spread" or "Return to Practice" (RTP) was fraudulently manipulated and increased by the manufacturer of Lupron (TAP) and how that spread incentivized providers such

[24] Medicare Payment Advisory Commission (MedPAC), Report to the Congress, *Variation and Innovation in Medicare*, June 2003 (*MedPAC Report*), pp. 156-157.

[25] That is, the *OIG Compliance Program Guidance*.

as urologists and oncologists to prescribe Lupron over alternative therapies have been well documented and admitted by Defendants in that matter and are helpful in understanding what occurred here as well. AWP was increased well above the estimated acquisition cost (EAC) or the average sales price (ASP) to the providers. Provider reimbursement rates were linked to AWP; ASP was decreased by substantial discounts, rebates, off-invoice payments and some admittedly illegal practices; TAP instructed the physicians dispensing Lupron and earning the inflated Return to Practice not to mention the aggressive price discounting to other doctors, to HCFA or to other payors (as discussed more fully in Section III.B below).[26] The resulting spread did incentivize the appropriate economic entities (physicians) to increase sales of Lupron relative to alternative therapies; market sales and market share were increased thereby. Indeed, some oncologists were named Defendants who earned millions of dollars in incentive payments from the "spread" or "Return to Practice."

24. Lupron's therapeutic competitor is the Track 1 drug, Zoladex, produced by AstraZeneca (AZ). As discussed below, to compete with Lupron, AZ adopted the same "Return to Practice" strategy, a practice which the independent expert to the Court, Dr. Berndt, has characterized (at his p. 46) as specific "egregious examples of fraudulent pricing and marketing involving sales of Lupron and Zoladex to physicians." AZ also entered into a settlement agreement with the federal government for such fraudulent marketing practices.[27]

The 2003 *MedPAC Report* summarizes the spread competition between Lupron and Zoladex as follows:

[26] All of these allegations are discussed in the *Lupron Sentencing Memorandum*.

[27] *Memorandum of Plea Agreement, United States of America v. AstraZeneca Pharmaceuticals LP*, In the United States District Court for the District of Delaware, Criminal Action No. 03-55-JJF, June 20, 2003 (Plaintiffs' Exhibit 1).

> "In October 2001, TAP Pharmaceutical Products, Inc. pleaded guilty to conspiring to violate the Prescription Drug Marketing Act. The central issue in the case was the allegation that TAP had encouraged urologists to bill Medicare for free samples provided by the company. TAP markets Lupron ..., a treatment for prostate cancer. Lupron competes with another drug called Zolodex .... In 2001, expenditures for Lupron and Zoladex were, respectively, the second and fourth highest of all drugs covered under Part B. Payments based on the easily manipulated average wholesale price (AWP) have allowed marketing abuses by manufacturers of these drugs. In the civil suit, the government alleged that the company had set AWPs far above the price that any of its customers paid and encouraged physicians to take advantage of the difference by billing Medicare for the AWP minus 5 percent. As part of its settlement with the federal government, TAP agreed to pay $875 million dollars to resolve criminal and civil liabilities in connection with its pricing and marketing of Lupron. More than a dozen former TAP employees are still under indictment for using kickbacks and bribes to get doctors to use Lupron rather than Zolodex. This litigation also has led to further lawsuits by the Attorneys General in many states. These as yet unresolved suits focus on the discrepancy between AWPs and the actual acquisition prices available to retailers. Similar charges have been filed against the makers of Zolodex. One physician pleaded guilty to billing Medicare for between $30,000 and $70,000 for free samples he received from the manufacturer (Bureau of National Affairs 2002)."[28]

25. The methods by which any other physician-related treatments (*e.g.*, other treatments for cancer; HIV/AIDS treatments; treatments for renal disease and hemophilia; treatments for transplant recipients; some nausea drugs; the use of nebulizers; and other therapies) would be incentivized are the same.

B. Spread Competition in This Matter Differs From Standard Price Competition and Does Not Benefit Consumers or Payors

26. Spread competition generally was strategically implemented by manufacturers once a drug manufacturer was confronted with competition from a new therapeutic or generic competitor. This type of competition must not be confused with normal price competition. While the spread competition in this matter may have involved competitive price reductions, it

[28] *MedPAC Report*, op. cit., p. 158.

C. Spread Competition was Practiced by Manufacturers of Single-Source and Multi-Source Drugs

30. Reimbursement for the Track 1 single-source drugs under Part B is subject to a single or sometimes limited number of J-codes (or other HCPCS codes), and has been based, until 2005, upon the lesser of some percentage of AWP and some measure of provider acquisition cost.[46] As a result, the AWPs and the ASPs for all NDCs of these drugs were

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A. We want to pay a rate that is – that is fair, reasonable and equitable to the provider, while at the same time controlling cost of care. …

A. And maintaining an adequate network, …"

Mr. Spahn's belief that his TPP pays a "rate that is … fair, reasonable and equitable to the provider, while at the same time controlling cost of care" reflects the understanding I find generally among TPPs in Class 3. Specifically, "every commercial transaction involves an element of trust," as noted by Daniel McFadden while quoting another Nobel Laureate, Kenneth Arrow. I discuss this "element of trust," its implications for Class 3 causation and damages, and the source of the quote in ¶¶ 98 & 99 below.

[46] It is useful to provide a brief summary of statutory provisions determining Medicare reimbursement for Part B drugs by time period.

Prior to 1992:

"Before 1992, Medicare carriers generally paid for drugs based on physicians' estimated costs as measured by the AWP." (Source: Medpac, "Report to Congress: Variation and Innovation in Medicare," Chapter 9, "Medicare payments for outpatient drugs under Part B," June 2003, pp. 152).

1992 through 1997:

"Payment for a drug … is based on the lower of the estimated acquisition cost or the national average wholesale price of the drug. … For multiple-source drugs, payment is based on the lower of the estimated acquisition cost … or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug." (Source: 42 CFR 405.517, Revised October 1, 1996).

From 1998 – 2003:

"Payment for a drug or biological … is based on the lower of the actual charge on the Medicare claim for benefits or 95 percent of the national average wholesale price of the drug or biological. … For multiple-source drugs and biologicals, for purposes of this regulation, the average wholesale price is defined as the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological. (Source: 42 CFR 405.517, Revised October 1, 2003).

For 2004:

"The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (DIMA) provides that as of January 1, 2004, the payment limits for drugs and biologicals are based on 85 percent of the April 1, 2003 Average Wholesale Price (AWP), for those drugs and biologicals furnished on and after January 1, 2004. … The Medicare payment limits [%*AWP] for drugs and biologicals not paid on a cost or prospective payment basis, and furnished on or after January 1, 2004, through December 31, 2004, are as described" for a variety of specific Part B medications, including blood clotting factors; new drugs or biologicals (as approved by the FDA

vulnerable to strategic manipulation by the manufacturer of that drug. The manufacturer of the drug could inflate the AWPs; reduce the ASPs; or do both, as discussed by the *MedPAC Report* as cited in my ¶ 22 above.

31. For multi-source (for the most part generic) physician-administered drugs reimbursed under Medicare Part B, reimbursement is generally based upon the lesser of some measure of provider acquisition cost and some percentage of the median of the AWPs of all generic sources of the drug.[47] Obviously, any manufacturer of a physician–administered multi-source drug can compete on spread by simply reducing its drug's ASP relative to the median AWP. In that case, the AWP inflation reflects the fact that reimbursement linked to the median AWP will invariably be inflated, usually substantially, relative to the provider acquisition cost. The question remains, can a multi-source manufacturer also inflate the AWP upon which reimbursement is based, everything else constant?

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subsequent to April 1, 2003); pneumococcal and hepatitis B drugs and biologicals; certain drugs studied by the OIG and GAO; infusion drugs furnished through an item of implanted durable medical equipment; drugs and biologicals not described above. The percentage off AWP for these different medications varies from 80-95%, some based on the April 1, 2003 AWP.

From § 20.2: "For a single source drug or biological, the AWP equals the AWP of the single product. For a multi-source drug or biological, the AWP is equal to the lesser of: the median AWP of all generic forms of the drug or biological; or the lowest brand name product AWP. (Source: Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 54, December 24, 2003).

From January 1, 2005:

"Per MMA of 2003, beginning 1/1/05, drugs and biologicals not paid on a cost or prospective payment basis will be paid based on 106% of the Average Sales Price (ASP). CMS will supply contractors with an ASP drug pricing file for payment of drugs. This pricing file shall be provided to contractors by CMS quarterly. Contractors will continue to price covered drugs not on the file." (Source: Department of Health & Human Services, Centers for Medicare & Medicaid Services, CMS Manual System, Pub. 100-04 Medicare Claims Processing, Transmittal 352, November 3, 2004).

[47] As discussed in the preceding footnote, reimbursement for multi-source physician-administered drugs was to be at the lesser of some percentage of the median of the AWPs of all generic sources of the drug and the lowest AWP of all branded sources. For most cases, the median of the generic AWPs was less than the lowest branded AWP.

require months of negotiation, which would be cost prohibitive. It is this impossibility and this cost-prohibitiveness that has been exploited by Defendants.

91. This market requires and relies upon simple rules of thumb regarding overall discounts off AWP for Classes of drugs, much like the resource-based relative-value scales (RBRVS) Medicare uses to make decisions regarding reimbursements to physician-service providers. As FDB says (see ¶ 15 above): "AWP was developed to provide a price, *which all parties could agree upon*" (emphasis added). The entities of this market can agree upon AWP, whether they know what it means or not. As a matter of economics, the question arises what is the average percentage off AWP that TPPs could have come to understand accurately reflected the acquisition costs of the providers (their ASPs) plus "some margin." The Court, Mr. Young and the TPPs themselves[137] admit that TPPs reimburse at AWP minus x%, where x% = (13%-18%) for single-source self-administered drugs. More importantly, Mr. Young and the TPPs admit that such reimbursement covers provider (pharmacy) acquisition costs (RAC ≈ WAC) and allows some profit to the providers (pharmacies).

92. What have Class 3 TPPs come to understand x% is and should be, so that physicians can cover their costs and perhaps earn a "reasonable margin" rather than "egregious profit" on the drugs they administer? This would be the rule of thumb that they would use when bargaining with providers. If manufacturers then secretly increased spreads such that reimbursement rates negotiated by TPPs with the expectation of an average spread of x% led in reality to "egregious" overcharges and profits unbeknownst to TPPs, by a rule of reason approach, it would seem that those secret spreads constitute fraud injuring the Class members.

[137] See the *Memorandum and Order*, at p. 63: "Hartman estimates that the range of actual reimbursement rates in TPP contracts with providers in the self-administered context was AWP minus 13% to 17% (Hartman Decl. ¶ 30(g)); Young uses the range of AWP minus 14% to 18% (Young ¶ 134)." See also ¶¶ 111-112 below.

Attachment G.3.a: Johnson & Johnson Annual Average Sales Price

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
00062740003	Procrit	PROCRIT 4000U/ML AMG	234.83	232.84	236.42										
00062740103	Procrit	PROCRIT 10000U/ML AMG	557.13	556.00	557.14										
00062740201	Procrit	PROCRIT 2000U/ML AMG	115.78	115.43	117.76										
00062740501	Procrit	PROCRIT 3000U/ML AMG	178.48	172.55	177.98										
59676030201	Procrit	PROCRIT 2000 U/ML 6'S				117.62	118.46	118.11	118.55	118.60	117.31	124.54	128.00	133.79	136.27
59676030202	Procrit	PROCRIT 2000 U/ML , INSTITUTIO			498.09	494.15	491.85	479.39		481.20	488.96	524.03	519.81	523.52	548.25
59676030301	Procrit	PROCRIT 3000 U/ML 6'S				176.05	176.90	176.89	177.53	177.72	176.26	185.68	191.29	199.58	202.65
59676030302	Procrit	PROCRIT 3000 U/ML 25'S			740.73	734.63	729.63	723.55		728.28	736.99	783.97	787.65	804.03	829.05
59676030401	Procrit	PROCRIT 4000 U/ML 6'S				234.81	236.78	236.72	237.63	238.04	235.70	247.46	254.95	265.18	269.20
59676030402	Procrit	PROCRIT 4000 U/ML 25'S			968.94	972.10	966.11	957.71		975.33	978.92	1,044.10	1,049.77	1,103.21	1,103.02
59676031001	Procrit	PROCRIT 10000 U/ML 6'S			557.07	558.14	561.71	560.24	577.87	592.60	584.54	615.53	634.83	660.26	664.16
59676031002	Procrit	PROCRIT 10000 U/ML 25'S			2,291.33	2,328.26	2,330.58	2,295.01		2,387.92	2,390.74	2,540.49	2,571.94	2,704.11	2,684.23
59676031201	Procrit	PROCRIT 10,000 U/ML , MULTIDOS				2,280.00	1,134.98	1,108.88	1,116.25	1,153.28	1,152.12	1,222.95	1,242.52	1,295.68	1,289.61
59676032001	Procrit	PROCRIT 20,000 U/ML - 1ML							1,146.79	1,151.70	1,146.06	1,195.10	1,226.31	1,276.48	1,272.45
59676034001	Procrit	PROCRIT 40000 U/ML 4'S									1,542.82	1,599.22	1,638.21	1,702.78	1,696.19
57894003001	Remicade	C168J REMICADE 1PCK US PD								450.68	462.77	499.15	524.32	532.24	532.18

Attachment G.3.c: Johnson & Johnson Annual Spreads

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
00062740003	Procrit	PROCRIT 4000U/ML AMG	22.6%	23.7%	21.8%										
00062740103	Procrit	PROCRIT 10000U/ML AMG	22.8%	23.0%	22.8%										
00062740201	Procrit	PROCRIT 2000U/ML AMG	24.4%	24.8%	22.3%										
00062740501	Procrit	PROCRIT 3000U/ML AMG	21.0%	25.2%	21.4%										
59676030201	Procrit	PROCRIT 2000 U/ML 6'S				22.4%	21.6%	21.9%	21.5%	21.4%	22.8%	20.1%	21.0%	19.8%	17.6%
59676030202	Procrit	PROCRIT 2000 U/ML , INSTITUTIO			20.5%	21.4%	22.0%	25.2%		24.7%	22.7%	19.0%	24.1%	27.6%	21.8%
59676030301	Procrit	PROCRIT 3000 U/ML 6'S				22.7%	22.1%	22.1%	21.7%	21.5%	22.5%	20.9%	21.4%	20.5%	18.6%
59676030302	Procrit	PROCRIT 3000 U/ML 25'S			21.5%	22.5%	23.4%	24.4%		23.6%	22.1%	19.3%	22.9%	24.6%	20.8%
59676030401	Procrit	PROCRIT 4000 U/ML 6'S				22.7%	21.6%	21.7%	21.2%	21.0%	22.2%	20.9%	21.5%	20.9%	19.1%
59676030402	Procrit	PROCRIT 4000 U/ML 25'S			23.8%	23.4%	24.2%	25.3%		23.0%	22.6%	19.4%	22.9%	21.1%	21.1%
59676031001	Procrit	PROCRIT 10000 U/ML 6'S			22.8%	22.5%	21.8%	22.1%	22.5%	21.5%	23.2%	21.5%	22.0%	21.4%	20.7%
59676031002	Procrit	PROCRIT 10000 U/ML 25'S			24.4%	22.4%	22.3%	24.2%		25.6%	25.5%	22.7%	25.4%	23.5%	24.4%
59676031201	Procrit	PROCRIT 10,000 U/ML ,MULTIDOS					20.5%	23.4%	26.8%	24.9%	25.0%	22.3%	24.6%	23.7%	24.3%
59676032001	Procrit	PROCRIT 20,000 U/ML - 1ML							23.4%	25.0%	25.6%	25.2%	26.3%	25.6%	26.0%
59676034001	Procrit	PROCRIT 40000 U/ML 4'S									24.4%	24.7%	26.0%	25.5%	26.0%
57894003001	Remicade	C168J REMICADE 1PCK US PD								29.8%	32.1%	28.5%	31.9%	29.9%	30.0%

Attachment I.3: Johnson & Johnson Drugs Subject to Liability

In the table below, "X" indicates a year in which a given NDC was subject to liability for Class 3.

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
00062740003	Procrit	PROCRIT 4000U/ML AMG													
00062740103	Procrit	PROCRIT 10000U/ML AMG													
00062740201	Procrit	PROCRIT 2000U/ML AMG													
00062740501	Procrit	PROCRIT 3000U/ML AMG													
59676030201	Procrit	PROCRIT 2000 U/ML 6'S													
59676030202	Procrit	PROCRIT 2000 U/ML , INSTITUTIO													
59676030301	Procrit	PROCRIT 3000 U/ML 6'S													
59676030302	Procrit	PROCRIT 3000 U/ML 25'S													
59676030401	Procrit	PROCRIT 4000 U/ML 6'S													
59676030402	Procrit	PROCRIT 4000 U/ML 25'S													
59676031001	Procrit	PROCRIT 10000 U/ML 6'S													
59676031002	Procrit	PROCRIT 10000 U/ML 25'S													
59676031201	Procrit	PROCRIT 10,000 U/ML , MULTIDOS													
59676032001	Procrit	PROCRIT 20,000 U/ML - 1ML													
59676034001	Procrit	PROCRIT 40000 U/ML 4'S													
57894003001	Remicade	C168J REMICADE 1PCK US PD									X		X		

TAB C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re:	)	
PHARMACEUTICAL INDUSTRY	)	CA No. 01-12257-PBS
AVERAGE WHOLESALE PRICE	)	MDL No. 1456
LITIGATION	)	Pages 8-1 - 8-175

BENCH TRIAL - DAY EIGHT

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
November 20, 2006, 9:15 a.m.

LEE A. MARZILLI
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I N D E X

right now. I think it's C-2. And so the initial setting of the AWPs and the amounts that were going to be reimbursed off of AWP were a 100 percent and then 95 percent, 85 percent. These were ratios that reflected, as best CMS and HCFA could tell, what would be a reasonable relationship between reimbursement and what AWP was signaling. And obviously over the duration of the '90s, a variety of studies were done that started to inform CMS that there was divergence for some drugs, and the extent of that divergence was unclear. And it does not make sense when AWP informs -- the AWP system is a leviathan -- it informs all the reimbursement throughout the public and private sector -- that they could not change different components of that without radically altering the incentives that are built into an RBRV system. So they responded with some inertia. They wanted to observe and be fully informed before they were to totally change a system.

Q. Slide 6. I'd now like to just talk about one aspect of incentives, Dr. Hartman. Of course, there's been testimony in the case about incentives for brand-name single-source drugs to have a wider spread from one to another. There's been some testimony about that. I'm not going to get into that. Instead I'd like to turn to something else, Slide 7.

There is testimony in your direct materials regarding the strategic manipulation of the spread by manufacturers of branded drugs -- and then, excuse me, I have

THE COURT: So you're not sure?

THE WITNESS: I can't recall exactly.

Q. Does the fact that in this case you're modeling damages over a twelve-year period affect whether or not taking a single one year's AWP and using that for the whole class period have an effect on whether or not you have a level of comfort regarding the accuracy of the ultimate damage number?

A. I'm very comfortable with these damage calculations. I have done similar damage calculations, and I think, say, for Lupron, I did them quarterly and annually. And you get more or less, you get the same number. It might be a few thousand dollars off or whatever, one percent off; but for purposes of what you're getting at, it is sufficiently accurate to give you the order of magnitude of the quantity you're looking at.

Q. Now, just go to Slide 20. This is just one example, Dr. Hartman, I take it, of Attachment G. We're really just showing this to the Court so that she can visualize your depiction of the AWPs used for your model; is that fair to say?

A. It is.

Q. And you've, of course, then set forth in that attachment your AWPs? If you go to, for instance, Slide 21. The importance isn't obviously to read the numbers here, but you've shown to the Court the AWPs that you used for each of the NDCs in this case for each of the manufacturers?

A. Correct.

Q. So again please describe to the Court what that approach entailed.

A. Well, that approach entailed getting as much information from contracts as I could get and finding what the third-party payors committed to in their negotiations with providers related to what they were going to reimburse off of AWP, revealing something of what they felt the costs were.

Q. And why is it that looking to what third-party payors did in fact is informative for your potential conservative threshold for single-source brand drugs?

A. Well, I take this as a measure of the revealed preferences or revealed negotiations of what the spread was.

Q. Okay. And is that a technique commonly used in applied economics?

A. Yes.

Q. Slide 87. On the basis of your analysis of each of these three prongs, Dr. Hartman, I've shown at Slide 87 your conclusion. Please describe to the Court what you concluded was a reasonable range of spreads expected in the third-party payor marketplace.

A. The preponderance of the evidence from all three of those sources, I used the First Databank AWPs, which at times diverged from the Red Book, but using based on First Databank, I found spreads in the range of 11 to 25 percent

TAB D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

In Re:	)	
PHARMACEUTICAL INDUSTRY	)	CA No. 01-12257-PBS
AVERAGE WHOLESALE PRICE	)	MDL No. 1456
LITIGATION	)	Pages 9-1 - 9-144

BENCH TRIAL - DAY NINE

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
November 21, 2006, 9:10 a.m.

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I N D E X

MR. HENDERSON: I think, to the extent that the defendants knew or heard things, that's fine. But to the extent that government people thought things, the government is a big entity, your Honor. It includes Congress, the Executive Branch --

THE COURT: I understand. I'm just talking about the people who ran the Medicare program. That's what I'm interested in, the people who ran it. So I'm assuming I will see requests for Rule 45 trial subpoenas for March. You'll have to let me know if someone's willing to voluntarily appear. It seems as if the ethical rule will permit reasonable compensation, but that doesn't mean paying someone like an expert. The cases tend to be informants in drug cases. They don't tend to be $300 an hour, which is what you pay an expert in a case or something. So I will allow reasonable compensation but no guarantee of the 300 bucks an hour.

So you're just going to have to let me know if this guy is willing to testify, and also I don't know very much about him and how relevant he is. I mean, I don't know, but he isn't the key periods of time, right? He's early on?

MR. MONTGOMERY: His employment with HCFA runs through 1998.

MR. EDWARDS: '84 to '98, your Honor.

THE COURT: Oh.

MR. MONTGOMERY: And, you know, I just might --

THE COURT: Then if he comes up, I'm likely to let him testify. And you can object to deliberative process privilege all you want because I know that privilege. I used to litigate that privilege myself. I know the balancing, I know the privilege, and we'll just do it question by question. But I'm not --

MR. HENDERSON: You're talking next week?

THE COURT: I don't know when that will be.

MR. MONTGOMERY: Well, we'll let you know. I would like to add, because it's not in the record yet, your Honor, that there is a case just decided two weeks ago in the Eastern District of California, U.S. V. Los Angeles County, a qui tam case, in which the government permitted Mr. Scully to testify with respect to the meaning of the Medicaid statute. And I think we've got an instance here in which the government is trying to preclude the testimony of witnesses when it suits their purpose but permit those very same witnesses to testify in similar issues.

THE COURT: Well, I haven't seen that. You can pass it up.

MR. MONTGOMERY: I am going to pass it up.

THE COURT: For me, the big thing me is, we've had five years of discovery. I ruled before. We're not starting with depositions. So to the extent that that's what we're

talking about, we're not doing it. However, I have another trial coming up, and I've got Track Two coming up. I've got -- there he is, all right, sitting here in the wings, literally. So I think it's important, and it's going to come out. It's just a question of time in the Ven-A-Care case, right? Then you are a party. We've got two Ven-A-Care, California and Florida. So I don't want to hear about it a year from now and then think I've done an injustice. That's my thing. So that's how I'm balancing it out. We are not sitting tomorrow. We are going to enjoy, and we are going to try and finish Dr. Hartman today. Yes?

MR. SOBOL: If I may, your Honor, I'm not sure then how the Court's rulings leave the situation regarding this Mr. Weintraub.

THE COURT: If they can get him to come in, I will allow him to testify. It's heartland information, from my point of view, subject to the deliberative process privilege. We will let the government come in and let the government object, and I'll have to just do it microscript by microscript as we go. But I'm not guaranteeing you 300 bucks an hour.

MR. MONTGOMERY: And, your Honor, we will let you know next week what arrangements, if any, we propose as to Mr. Weintraub. We, of course, do object to your Honor's unwillingness to issue trial subpoenas to these witnesses.

We think their testimony has become particularly relevant as the trial has proceeded.

THE COURT: I think it's been relevant from the get-go. It's been the issue from the beginning. I rule no more depositions. And as I understand it, I can't bring them in here under any theory. It would have to be depositions somewhere else, and then I'd either see the video deposition or whatever.

MR. MONTGOMERY: It could be trial testimony by video.

THE COURT: It's too late for all that, but it's not too late for the next trial. And so as far as this guy Weintraub, just you'll have to give the government fair notice as to whether he's willing to come in or not. And you don't know, do you, whether he's willing to?

MR. HENDERSON: No, I don't. Whether Mr. Weintraub is willing?

THE COURT: Yes.

MR. HENDERSON: I don't know, your Honor.

THE COURT: Does anyone know what he's going to say?

MR. HENDERSON: I've seen his affidavit that the defense submitted in another case.

MR. MONTGOMERY: Well, we can certainly make a proffer as to what we would expect him to say. I can say, as

to Mr. Jennings, another witness that we've talked about, is that Mr. Jennings, particularly in light of the communications he's had with the Justice Department, is not willing to testify at the behest of the defendants. Your Honor, if you asked him to come, he would come.

THE COURT: Did he run for Congress?

MR. MONTGOMERY: No.

THE COURT: I'm thinking of someone else.

MR. MONTGOMERY: Not that I'm aware of. Mr. Jennings was the domestic policy advisor for health care --

THE COURT: I don't know him then.

MR. MONTGOMERY: But, as I said, I believe Mr. Jennings would come if he were subpoenaed or if the Court asked him to come.

THE COURT: The next trial, we may be there. It's too late now. So as a matter of discretion, I'm not starting it midway, but you can bring to trial whomever you want, and we'll see where we go.

Okay, now let's get to Dr. Hartman.

RAYMOND S. HARTMAN

having been previously duly sworn, was examined and testified further as follows:

CONTINUED CROSS-EXAMINATION BY MR. EDWARDS:

Q. How are you today, Dr. Hartman?

ways of practices and procedures are put in place with the aim of accomplishing certain results, certain objectives; and one looks for evidence over time to see whether they're working. And whether we're looking at foreign policy for this country or we're looking for strategic policy for a pharmaceutical company, certain strategies are put in place. You look for evidence. But when one piece of evidence comes in, you don't suddenly say, "Okay, I now know that everything that I thought I was doing is wrong." There's an incremental gathering of information that leads to a systematic understanding. So you're trying to say one piece of evidence made HCFA aware and that should change the world for them. Institutions don't work that way.

THE COURT: Okay, now, we are never going to finish today. So you need to answer yes or no.

THE WITNESS: Just say yes or no, okay.

THE COURT: You need to move at a faster clip. The rest of them need a go at it too, all right?

MR. EDWARDS: Yes, your Honor.

THE COURT: So how long have you charged yourself?

MR. EDWARDS: Well, I'm going to try to finish in two hours. But you're absolutely correct. If I can't get one-sentence answers to my questions --

THE COURT: No, you can control too. So I don't want to be the one who's got the control thing, so we're

going to finish today. So are you doing it for everyone, and then everybody's going to do a cleanup? How is it working?

MR. EDWARDS: That's the way it's working, your Honor.

THE COURT: You are finishing at 11:00. So you are each going to get 11:30 to 12:00, 12:30 to 1:00, a half an hour apiece.

MR. EDWARDS: Your Honor, I'm going to try my best.

THE COURT: No, you're going to, and then you can control him. And you're not going to talk as much because otherwise you have to come back.

MR. SOBOL: And me?

THE COURT: You get fifteen minutes at the end somewhere there, or you can bring him back when you want. You're probably going to do it on rebuttal anyway, right? So I'll worry about that later, but I need you to just move at a clip. Let's go.

MR. EDWARDS: Your Honor, we offer Defendants' Exhibit 1881. That's the Ven-A-Care letter.

THE COURT: Fine, without the attachment.

MR. SOBOL: Objection, your Honor, or just take it de bene subject to a motion to strike later based--

THE COURT: Overruled. I'll allow in the letter, not for whether it's true but what HCFA was on inquiry notice of. For purposes of statute of limitations, I need to

THE COURT: All right, what's the next question?

Q. Now, you'd have to admit, Dr. Hartman, that the spreads revealed in these documents were large and indeed sometimes substantially large?

A. I -- I agree. I've stated it in my direct testimony.

Q. Okay. And you would also agree that during the 1990s, the relevant Medicare agencies were presented with increasingly compelling and consistent information sufficient to make it clear that AWP was no longer the reliable benchmark it had been and had been believed to be? You would agree with that, correct?

A. It seems very well put.

Q. Now, under your theory of liability for Class 2, every prescription drug in the United States would violate the rules, correct?

MR. SOBOL: Objection.

THE COURT: Overruled.

A. Under my theory of the plain meaning rule, every drug would violate the -- under the plain meaning rule, there are damages for every unit reimbursed above ASP.

Q. And every drug would have an AWP above ASP, correct?

A. I hesitate to say "every," but most.

Q. And that's because AWP is always going to be 20 to 25 percent above WAC, correct?

A. For the most part.

for Procrit were above your 30 percent yardstick, right?
A. I -- I'd have to go back and look at which chart you're talking about.
Q. Okay, that's fine. Will you accept my representation that it was 16 out of 114?
A. I have no basis to accept it or reject it. I'd have to look at --
Q. Fine. Let's go to where you are today on Procrit. If we could go to I-3, please.
THE COURT: So this is in your wish list?
MR. CAVANAUGH: Yes, your Honor.
A. And is there a tab?
Q. It's Hartman trial declaration. It's your Attachment 1.3.
THE COURT: What happens when these get taller than me?
MR. CAVANAUGH: It's his trial declaration.
MR. SOBOL: All right.
Q. Now, these are the spreads that you put an X if it's over 30 percent, right?
A. That's correct.
Q. All right, so for Procrit we have none?
A. It looks like that's true.
Q. So Procrit is out of Class 3, right?
A. It does not -- none of the NDCs exceed the 30 percent

spread.

Q. All right, so as you understand it, it's out of Class 3?

A. I have not included it in Class 3, so that's --

Q. All right. Now, let's look at what you have now calculated as your Procrit spreads. If we could go to Attachment G-3C, please, to your trial declaration. We're going to put it up on the screen. These are the spreads that you've now calculated.

A. Could you tell me where they are here? It's easier for me to see them in the paper.

Q. Is your trial declaration attached there?

THE COURT: They're in your tab, the second tab in.

MR. CAVANAUGH: All the attachments -- it appears actually --

Q. Now, Doctor, what I've done is, I have counted up your spread calculations for Procrit, and if we could just go to that, I've highlighted the ones that are over 25 percent, and this is how they break down.

A. Okay.

Q. You don't have any reason to disagree with that, do you?

A. I assume you've done your taxonomy correctly.

Q. All right. Now, Medicare was also aware of Procrit's spreads, were they not?

A. Medicare was -- had expectations that I've discussed in

my direct testimony.

Q. All right. But specifically they were given information about differences between Procrit's AWP and its selling price, were they not?

A. In what form are you talking about?

Q. Well, let's go to the 1997 OIG report, DX 1075, which is in evidence already, your Honor. And this is from Attachments B and 3, and B-3 -- DX 1075. And I've highlighted Q0136. Do you see that? That's Procrit and Epogen in nondialysis.

A. I will -- I don't have the J-Codes here. I see -- oh, there we go.

Q. Okay?

THE COURT: Now, where am I looking?

MR. CAVANAUGH: Your Honor, I've created a demonstrative based upon this data, so if you go to your demonstrative tabs, it would be D3 and D4, if you go DD3 and 4.

Q. So what I've done here, Dr. Hartman, is, I've calculated based upon how you calculate spreads for all of these drugs in the '95 and '96 calculations done by OIG in 1997. And you see for Procrit, Q0136, the spreads range from 20 to 34 percent. The lowest wholesale price produces what I'll call a Hartman spread of 34.8. So Medicare was certainly aware that there were differences between Procrit's AWP and

its selling price, correct?

A. The OIG certainly published a report of this sort that has this information.

Q. Now, let's turn to -- well, let me ask you a further question. And would you agree with me that if the Court applies your 30 percent yardstick to Procrit, there would be no damages for Procrit for Class 2?

A. If the Court were to say that on average there's no liability should spreads exceed 30 percent, then these spreads do not exceed 30 percent.

Q. So Procrit would be out of the case, okay. Let's turn to Remicade. Now, you agree with me that you originally started with a 33 percent expectation theory?

A. No.

Q. All right, well, let's go to Judge Saris' opinion, if we could. This is Judge Saris' opinion from class certification. She refers to the expected AWP minus 16 percent to 33 percent threshold.

THE COURT: Was I talking about self-administered or physician-administered then? Do you remember?

THE WITNESS: I can clarify that.

THE COURT: The reason is, I said retailers --

THE WITNESS: Well, I had speculated, I had looked at some very preliminary sources of yardstick information. I had made some assumptions about rebates, and this was

under your approach, there's two speeding tickets --

MR. CAVANAUGH: Your Honor, that's demonstrative DD 6.

A. That's right.

Q. Okay, so you would give Centocor speeding tickets in 1999 and 2001 but not in the other years, correct?

A. When I see that any drug has exceeded what is a conservative threshold, a speeding ticket is issued.

Q. Now, you'd agree with me that the key to your -- one of your findings here is that there was a lack of price transparency in the physician-administered drug market, right?

A. That's correct.

Q. And, in your view, the spread must be increased secretly, right?

A. The spread, the size of the spread, as quotes from your own -- from the former Centocor marketing director, which I cite in Paragraph 56 and 59 of my direct testimony, says: Look, we want to move some market share, and let's not show this to people that they get an idea of what's going on. So there's secrecy involved there.

Q. Now, let's talk about what information was available. You'd agree with me that throughout this period 1998 to 2003, there was a published AWP and a published WAC for Remicade, right?

A. Yes.
Q. All right. And there was a 30 percent difference spread, right?
A. That's correct.
Q. So the 30 percent spread was publicly available?
THE COURT: And what year is this?
MR. CAVANAUGH: Throughout the entire period.
THE COURT: Are these in the red books, you mean?
MR. CAVANAUGH: Yes, and First Databank.
A. That information would have been available to someone who sought it out and didn't assume that the spread was closer to Procrit.
Q. But First Databank, Red Book, they're widely used services, are they not?
A. They are.
THE COURT: So the spread in there was 30 percent?
THE WITNESS: The spread in -- I believe the spread was 30 percent with AWP WAC spread for Remicade.
Q. If we could go to DX 2782, which is the plaintiffs' response to our request for admissions, at Page 3. It's on your screen, Dr. Hartman. We asked the plaintiffs to admit that "From 1998 to the present, the published AWP for Remicade has been 130 percent of the published WAC for Remicade." And plaintiffs' response was that that was admitted, right?

A. That's right.
Q. All right. So that wasn't a secret.
A. Well, let me just --
Q. Let's --
THE COURT: No. How could that be a secret?
THE WITNESS: Well, why don't I quote -- partially it is, how much do the payors go to these sources and find out this information? Because I'm quoting -- if this were not supposed to be a secret, I cite, again, Centocor's senior director --
THE COURT: Okay, so --
THE WITNESS: -- and say, look, we want to keep that straight, we want to manage expectations and keep payors' expectations so that they don't know that there's this spread.
Q. But, Dr. Hartman, your theory is that payors had a 30 percent expectation. Isn't that your theory?
A. No. My theory is that the ranges of expectations one saw were anywhere from 11 to 12 percent to 27 percent, and I took an upper bound of 30 percent.
Q. So it was within the range of payor expectation, in accordance with the yardstick you're applying in this case?
A. It -- it was -- it was -- it hits the conservative limit, speed limit that I took that's in excess of the expectations I found.

Q. Okay, I know you like the word "conservative." Yesterday I thought you and Mr. Sobol were auditioning for Fox News. You used the term "conservative" nineteen times.

MR. SOBOL: Oh, that's a low blow.

(Laughter.)

MR. CAVANAUGH: I understand this is a PBS kind of town.

THE WITNESS: It's NPR, please.

MR. CAVANAUGH: Sorry.

Q. Okay, let's go back to -- now, you said you did a hedonic analysis, right?

A. Yes.

Q. Did you do a hedonic analysis as to the difference -- can we get DD 6 back up here. Did you do a hedonic analysis as to the difference between 30 percent and 31.9 percent?

A. No.

Q. Okay. Now, you're aware Centocor didn't give rebates or discounts to physicians, correct?

A. I'm aware that we -- we found information in your database that suggested that there were price offsets, but we were continually told by the experts with whom and the people with whom we interacted that no, no, no, they're not. And so we gave up trying and just accepted what your expert -- we couldn't confirm that, but we accepted what Mr. Duke's --

Q. Well, Mr. Hoffman came here and testified to the Court

that Centocor gave no discounts or rebates to physicians, and you don't have any basis to disagree with that, do you?

A. I've not -- we didn't get the data to evaluate that, so if he says that and it's --

Q. Well, if there's no discounts or rebates given, there would be no data to evaluate, correct?

A. There were negative -- there was data in -- there were offsets in the data which we couldn't explain, and we were told it was --

THE COURT: So basically you didn't give any discounts or rebates, or did you?

THE WITNESS: We didn't give them. We took them out. But we couldn't tell whether what we were taking out really was a discount or not. We couldn't make --

THE COURT: This is a nonissue. They didn't subtract it.

MR. CAVANAUGH: I understand.

Q. Well, how do you explain getting to your 32.1 and your 31.9 for those two years?

A. We followed the directions of your people, and we responded where we could to Mr. Duke's review of what we had done, and we incorporated that. We've explained those adjustments fully, and we get these results.

Q. And these are prices to specialty distributors and wholesalers, correct?

discounts in that way. If there's a -- if someone is -- if J & J says, I want to increase discounts in order to move market share in a particular way or to finance practice enhancement programs, and they move their discounts in that way to do it, then that is a use of the spread that is in violation of my yardstick.

Q. You weren't listening to my question. My question was, assume a drug, 25 percent spread between WAC and AWP. The manufacturer offers a 3.8 percent discount to get up to your 30 percent spread, okay?

A. Right.

Q. The manufacturer then takes the giant step of going from 3.8 percent to 4 percent. They have now violated your yardstick, and you would attach liability, correct, by making a .2 percent increase in their discount?

THE COURT: Assume his math.

A. If they have decided to go from 25 percent to above 30 percent -- you're starting at a point that's already at 30 percent, so the point is, really, how much above 25 percent are they going? And, yes, if they're getting close, if they're pushing that envelope, I'm going to try and get close to the speed -- I'm going through a school zone, and I'm going to get close to 30, but, you know, I'm just going to push it up, I'm just going to jack it up to 31 miles an hour.

THE COURT: So the answer is "yes," you think there is liability?

THE WITNESS: Yes.

Q. Let's go to how you calculated the AWPs. Now, you gave some testimony about this, and I'm going to put up a demonstrative, DD 9.

THE COURT: Is there something to the DD? Is there a -- no?

MR. CAVANAUGH: They tell me it's DD 9, Judge.

Q. Now, one of the years where you found -- where you'd issue a speeding ticket would be 1999.

THE COURT: Actually, is it DD 10? I don't know that I have it.

THE WITNESS: I have DD 7. Oh, here it is. I see.

Q. Have you got it?

A. Yes.

MR. CAVANAUGH: Your Honor, did you find it? It's in the beginning.

(Discussion off the record.)

THE COURT: Good. Thank you.

Q. Now, one of the years where you found an increase was 1999. It's 2.1 percent over the published WAC. And what you did is, you selected the AWP that was in effect on June 30 of the year, correct?

A. That's correct.

were to proceed on a quarterly basis or a monthly basis and taken the AWPs that were in existence at that point, there would always be some issue of some sales that occurred earlier to its posting being below a certain level of the ASP and some after it being higher, and so we're taking averages here.

Q. Dr. Hartman, I understand, but you didn't take an average of AWPs. You took one AWP, and you took the AWP that was in effect on June 30, right?

A. In the middle of the year, that's right.

Q. In the middle of the year, even though there had been a lower AWP for half of the year, roughly, because the price increase wasn't until June 18?

A. And could you tell me why --

THE COURT: No, there's no question. What's the next question because you're practically done?

MR. CAVANAUGH: That's fine.

Q. Next page, let's go to DD 10.

A. You're skipping 2000, I see, where the same factors should apply, if you're hypothesis is right. And if this is biasing it upward, it should be throughout, and we're not seeing --

Q. Oh, but, Dr. Hartman, they would have to take a price increase in that year, wouldn't they? And it would depend on when they -- this is based upon a price increase. These are

the two years that you found them over 30 percent. So let's go to 2001, which is the other year when you found them over 30 percent. You did the exact same thing, didn't you? There was a price increase on June 6 that raised the AWP and the WAC, and you then compared -- to arrive at your spread, you used the higher AWP and compared it to sales that were made before June 6 at a lower WAC, right?

A. I will -- the -- what I've done is, I've used the AWP as posted, and it's important for me to get this point across; that I take every year the AWP that's posted in the middle of the year and compare it to the ASPs over the year as a whole, and I observe how manufacturers change their AWPs over time. If you're telling me that they only raised their AWP in 1999, and then they kept it constant through 2000, and then they raised it again in 2001, which is kind of what I'm hearing, then I'm hearing you say that essentially we shouldn't even have proceeded annually. We should have done this for the period as a whole --

Q. Dr. Hartman, you have proposed annual spreads for Remicade. And for 1999 and 2001, the only two years in which you find them over 30 percent by a percentage point or two, you've used not an average of AWPs; you've used the AWP that was in effect after a price increase had been taken, correct?

A. That's correct.

THE COURT: Thank you. Are you done?